



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,506	05/06/2004	Rafail Zubok	SPINE 3.0-455	2911
530 7590 09/17/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 09/17/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/781,506

**Applicant(s)**

ZUBOK ET AL.

**Examiner**

JERRY CUMBERLEDGE

**Art Unit**

3733

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9, 10, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 4-8 and 11-13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 9, 10, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US Pat. 6,425,920 B1) in view of Marnay (US Pat. 5,314,477).

Hamada discloses a system comprising a cervical disc replacement device (Fig. 33, ref. 211); an insertion handle (Fig. 33, ref. 401) comprising a shaft (Fig. 33) having a proximal end (Fig. 33, near ref. 431), a distal end (Fig. 33, near ref. 409), a longitudinal bore (Fig. 33, near ref. 427) extending from the proximal end toward the distal end (Fig. 33), and an actuator (Fig. 33, ref. 429) disposed substantially at the proximal end of the shaft and an engagement member (Fig. 33, ref. 409) disposed at the distal end of the shaft; an insertion plate (Fig. 33, ref. 412, 405), the insertion plate operable for detachable engagement with the insertion handle (Fig. 33, when unscrewed); and a pushing member (Fig. 33, ref. 423) having a proximal end and a distal end (Fig. 33) and being slideably receivable within the longitudinal bore (Fig. 33). The shaft is operable to permit the first and second members of the intervertebral disc replacement device to be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (Fig. 33). The

insertion handle is detachable from the insertion plate to facilitate removal of the insertion handle when the intervertebral disc replacement device is positioned within the intervertebral disc space (Fig. 33). The actuator is operable to cause the shaft and the insertion plate to disengage from one another (Fig. 33, if turned enough times to unscrew the plate from the shaft). Actuation of the proximal end of the pushing member causes the distal end thereof to engage the insertion plate and separate the shaft from the insertion plate (Fig. 33).

Hamada discloses a system comprising: a cervical disc replacement device (Fig. 33, ref. 211); an insertion handle (Fig. 33, ref. 401) having a shaft (Fig. 33) having a proximal end (Fig. 33), a distal end (Fig. 33), and a longitudinal bore (Fig. 33, bore near ref. 427) extending from the proximal the distal end of the shaft (Fig. 33); and an insertion plate (Fig. 33, ref. 412, 405) having a base (Fig. 33) having a posteriorly directed surface directed toward the first and second members of the intervertebral disc replacement device (surface facing ref. 213), a spaced apart anteriorly directed surface (Fig. 33, near ref. 411), and an insertion member extending away from the anteriorly directed surface of the base (Fig. 33, near ref. 421), the insertion plate operable for detachable engagement with the insertion handle (Fig. 33, when completely unscrewed).

Hamada discloses a system comprising: a cervical disc replacement device (Fig. 33, ref. 211); an insertion handle (Fig. 33, ref. 401) comprising a shaft (Fig. 33) having a proximal end (Fig. 33), a distal end (Fig. 33), a longitudinal bore (Fig. 33, bore near ref. 427) extending from the proximal end toward the distal end, and an actuator (Fig. 33,

ref. 429) disposed substantially at the proximal end of the shaft (Fig. 33) and an engagement member (Fig. 33, near ref. 409) disposed at the distal end of the shaft; an insertion plate (Fig. 33, ref. 412, 405) having a base (Fig. 33) having a posteriorly directed surface (Fig. 33, surface facing ref. 213) directed toward the first and second members of the intervertebral disc replacement device (Fig. 33), a spaced apart anteriorly directed surface (Fig. 33, near ref. 411), and an insertion member extending away from the anteriorly directed surface of the base (Fig. 3, near ref. 421), the insertion plate operable for detachable engagement with the insertion handle (Fig. 33, when completely unscrewed); and a pushing member having a proximal end and a distal end and being slideably receivable within the longitudinal bore (Fig. 33, ref. 423).

Hamada discloses the claimed invention except for the cervical disc replacement device having first and second members and the insertion plate connected with and maintaining the first and second members of the intervertebral disc replacement device in registration with one another for substantially simultaneous insertion into an intervertebral disc space of a spinal column. Hamada does, however, disclose that the device comprises an implant that is used in a corrective spinal procedure (abstract).

Marnay discloses an insertion system (Fig. 10)(Fig 1) used to insert a disc replacement device (Fig. 1), the replacement device comprising first and second members (Fig. 1, ref. 110, 120), the replacement device being used in a corrective spinal procedure (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the disc replacement device of Hamada

with the disc replacement device of Marnay, in order to achieve the predictable result of using a replacement device in a corrective spinal procedure.

***Allowable Subject Matter***

Claims 4-8 and 11-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./  
Examiner, Art Unit 3733

/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733

